UNITED STATES PATENT AND TRADEMARK OFFICE

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Commissioner for Patents
United States Patent and Trademark Office
Washington, D.C. 20231
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Robert J. Baran
Allergan, Inc.
2525 Dupont Drive
Irvine CA 92612

Re: Patent Term Extension
Application for
U.S. Patent No. 5,089,509

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,089,509, which claims the human drug product TAZORAC® (tazarotene), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 845 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within thirty days of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 845 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of May 20, 1999 (64 Fed. Reg. 27578). Under 35 U.S.C. § 156(c):

Period of Extension = ½ (Testing Phase) + Approval Phase
= ½ (1958 - 740) + 726
= 1,335 days

Since the regulatory review period began February 8, 1990, before the patent issued (February 18, 1992), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From February 8, 1990 to February 18, 1992 is 740 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,335 days, would extend the patent from February 18, 2009 (35 U.S.C. § 154) to October 15, 2012, which is beyond the 14-year limit (the approval date is June 13, 1997, thus the 14 year limit is June 13, 2011). The period of extension is thus limited to June 13, 2011, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, February 18, 2009, to and including June 13, 2011, or 845 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 5,089,509

Granted:	February 18, 1992
Original Expiration Date[1]:	February 18, 2009
Applicant:	Roshantha A. S. Chandraratna
Owner of Record:	Allergan, Inc.
Title:	Disubstituted Acetylenes Bearing Heteroaromatic and Heterobicyclic Groups Having Retinoid Like Activity
Classification:	514/337
Product Trade Name:	TAZORAC® (tazarotene)
Term Extended:	845 days
Expiration Date of Extension:	June 13, 2011

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: TAZORAC® (tazarotene)
FDA Docket No.: 98E-0474

[1]Subject to the provisions of 35 U.S.C. § 41(b).